REMARKS

Claims 1, 12 and 16 are pending. The support for the claim amendments are found in the published specification as follows: Claim 1: [0050]; and Claims 12: (clarification). No new matter has been added.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. (Office Action, page 2)

Claim 13 has been canceled, making this rejection now moot.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, page 3)

The expression PEO has been deleted from claim 12 and claim 13 has been canceled, making this rejection now moot.

Claims 1, 12-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20020106461 (`461) in view of US 5759583 (`583). (Office Action, page 6)

The claimed invention has been clarified to distinguish the claimed facilitation of phagocytic activity as compared with the sustained release delivery of the cited art. Thus it will be apparent that the invention now claimed is not obvious in light of the combination of cited art.

US'461 discloses:

> [0005] Pharmaceutical formulations that provide for delivery of a drug over an extended period of time have revolutionized the pharmaceutical industry. Whether the delivery is sustained, modified, controlled, extended, or delayed, the concept is generally the same--provide in a single dose what previously required multiple doses. ***("Sustained release" will be used herein to describe this generic class of release mechanisms.)*** The desire is to provide an effective concentration of the drug for an appropriate length of time. (emphasis added)

US'583, which concerns sustained release poly (lactic/glycolic) matrices, discloses in col. 1, lines 7 - 10:

> This invention relates to sustained release delivery systems, in particular poly(lactic/glycolic acid) (PLGA) delivery systems for the ***sustained release*** of bioactive agents. (emphasis added)

Both US'461 and US'583 disclose prior drugs which are aimed at "sustained release," so the finished products of the drugs must have distributed property.

In contrast, the ***claimed invention facilitates phagocytic activity of macrophages***, so the finished products of the claimed remedies are ***specialized for a specific property***. It is described in the instant specification:

> [0086] When actual treatment of the infectious disease is performed, a formulation in which a medicament of type (2) or (3) is contained in a remedy of type (1) is effective. That is, in order for the remedy of type (2) or (3) to effectively act in the macrophages, the remedy of type (1) facilitates the phagocytic activity of the macrophages to enhance the function which carries the remedy of type (2) or (3) into the macrophages. That is, as shown in FIG. 1, the remedy intended by the invention is easily phagocytosed by the macrophages, facilitates the phagocytic activity by being phagocytosed, and thus the concentration of the remedy in the macrophages becomes remarkably higher compared to the case of administering the remedy alone. ***That is, in comparison to the drug incorporated into the macrophages in a conventional drug solution on the right side, internal drug-including fine particles according to the invention on the left side are actively incorporated into the macrophages to increase the drug concentration in the macrophages.*** In this way, ***"facilitating the phagocytic activity of the macrophages" described in the Claims mean that the concentration of the remedy in the macrophages becomes remarkably higher compared to the case of administering the remedy alone*** because the remedy enhances the phagocytic capacity of the macrophages. (emphasis added)

Thus, sustained release drug delivery and sustained release matrices are completely different from facilitating phagocytic activity of macrophages as explained above. As a result, the cited combination of US'461 and US'583 cannot possibly create a *prima facie* rejection of obviousness for the invention now claimed.

In light of at least these differences of the claimed invention over the cited art, it is respectfully requested that the rejection be reconsidered and withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105.

Dated: August 10, 2009

Respectfully submitted,

Customer No. 21874

Electronic signature: /James E. Armstrong, IV/
James E. Armstrong, IV
Registration No.: 42,266
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(202) 478-7375
Attorneys/Agents For Applicant